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Analyzing Seated Pressure on Different Surfaces Using the FSA Pressure Mapping System

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ANALYZING SEATED PRESSURE ON DIFFERENT SURFACES
USING THE FSA PRESSURE MAPPING SYSTEM

by

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Bachelor of Science in Physical Therapy
University of North Dakota, 2006

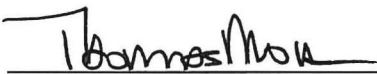
A Scholarly Project
Submitted to the Graduate Faculty
of the
University of North Dakota
in partial fulfillment of the requirements
for the degree of
Doctor of Physical Therapy

Grand Forks, North Dakota
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2008



This scholarly project, submitted by Christine Robinson, Sara Sailer, Jennifer Weber, and Amber Weide in partial fulfillment of the requirements for the Degree of Doctor of Physical Therapy from the University of North Dakota, has been read by the Faculty Advisor under whom the work has been done and is hereby approved.


Graduate Advisor


Chairperson

PERMISSION

Title Analyzing Seated Pressure on Different Surfaces Using the FSA Pressure Mapping System

Department Physical Therapy

Degree Doctor of Physical Therapy

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Date 12/12/07

TABLE OF CONTENTS

LIST OF FIGURES	vi
LIST OF TABLES	vii
ACKNOWLEDGMENTS	viii
ABSTRACT	x
CHAPTER	
I INTRODUCTION	1
Problem Statement	2
Purpose of the Study	2
Significance of the Study	2
Research Questions	3
Hypotheses	3
II LITERATURE REVIEW	4
III METHODOLOGY	13
Subjects	13
Inclusion/Exclusion Criteria	14
Instrumentation	14
Protocol/Procedure	18
Data Analysis	22
V RESULTS	23

VI	DISCUSSION AND CONCLUSION	26
	Limitations	27
	Suggestions for Future Research	28
	Clinical Implications/Conclusions	29
APPENDICES		
A	Poster	30
B	Consent Form	32
C	IRB Form	36
D	Data Collection Sheet	47
E	Output	49
REFERENCES		53

LIST OF FIGURES

Figure		Page
1	Homedics Micropedic Therapy Pillow	16
2	Force Sensitive Application Pressure Mapping System	17
3A	Front View of Adjusted Seating Posture	20
3B	Lateral View of Adjusted Seating Posture	21

LIST OF TABLES

Table		Page
1	Participants' Characteristics	14
2	Results of the Study	24

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Jennifer Weber, SPT

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ABSTRACT

Pressure ulcers are a current problem for many individuals, both ambulatory and non-ambulatory. Insurance companies offer few policies and programs for individuals with pressure ulcers who are ambulatory, leaving these individuals minimal options to acquire pressure relieving devices that are covered by insurance. Non-traditional, inexpensive pressure relieving devices may be used as a cost effective alternative to a more expensive cushion. Little research has been conducted to determine if a less expensive device, such as a Homedics Micropedic Therapy pillow, would be effective in relieving pressure while seated.

The purpose of this study was to determine if there was a significant difference between sitting pressure when seated on a hard surface, a surface with a built-in cushion, and a Homedics Micropedic Therapy pillow. One benefit of this study is to give physical therapists evidence based information on inexpensive pressure relieving devices in order to educate patients who are ambulatory and who may be at risk for a pressure ulcer.

Thirty-five ambulatory subjects between the ages of 23 and 55 sat on the three surfaces. A Force Sensitive Application (FSA) pressure mapping system was used to assess the mean pressure, the number of sensors activated, the variation of pressure, and the standard deviation of pressure for each seated surface.

Statistical significance was found in the measurements between all three surfaces, with one exception. When comparing the hard surface to the surface with a built-in cushion, there was no statistical significance in mean pressure. The results from this study showed that the Homedics Micropedic Therapy pillow is statistically significant for reducing seated pressure.

CHAPTER I

INTRODUCTION

Current research regarding pressure ulcer formation tends to revolve around non-ambulatory individuals but is lacking in the area of ambulatory individuals. In a study by David J. Margolis, et al.¹ Seventy-five thousand one hundred sixty-eight ambulatory individuals 65 years and older with medical conditions such as Alzheimer's disease, congestive heart failure, hip fracture, and malignancy but no current pressure ulcers were followed to record the incidence of pressure ulcer development. Out of the 75,168 older individuals followed, 1,211 individuals developed pressure ulcers. Under current Blue Cross Blue Shield² policy, these ambulatory individuals would not be covered by insurance to purchase pressure relieving cushions. Cushions can range from \$55.00 for a Jay Basic cushion to \$340.00 for a RoHo Quadtro Select High profile wheelchair cushion when purchased through rehabmart.com, a discount medical equipment website.³ Without insurance reimbursement individuals must choose to personally purchase a cushion, find a cheaper alternative or go without.

The cost of pressure ulcer treatment will far exceed the cost of an inexpensive cushion and/or other preventative measures. As of 2001, it is estimated that annually 1.2 billion dollars are spent within the United States on

pressure ulcer treatment.^{4,5} The cost to the individual ranges from medical bills, hospital stays, missed school or work, psychosocial issues of embarrassment, loss of independence, role reversal in homes, and permanent physiological impairments.⁶

Problem Statement

There is little research focusing on proper seating surfaces for ambulatory individuals who are at risk for developing pressure ulcers. At-risk individuals are those who have decreased sensation or difficulty weight-shifting for pressure relief. In work, school, and in play environment, there are multiple surfaces with differing levels of padding. Individuals may be unaware of how to select the most appropriate seating surface to minimize the risk of skin breakdown. While most research focuses on expensive pressure relieving devices, there is a lack of research available that analyzes inexpensive pressure relieving devices, which may be the only option for some individuals.

Purpose of the Study

The purpose of this research study was to determine if there was a significant difference between sitting pressure when seated on a hard surface, a surface with a built-in cushion, and a Homedics Micropedic Therapy pillow on a hard surface.

Significance of the Study

The information obtained from this study could assist health care practitioners by educating patients who are at a high risk for skin breakdown in selecting appropriate seating surfaces. The pressure relieving device used in

this study was a Homedics Micropedic Therapy pillow, an inexpensive pillow which can be easily obtained by people of all social classes. This study will allow physical therapists evidence based suggestions regarding an alternative, inexpensive and easily obtainable seating surface for their patients.

Research Questions

1. Is there a significant difference between the mean seated pressure, the number of sensors activated, the variation of pressure, and the standard deviation of pressure when seated on a hard surface, a surface with a built-in cushion, and a Homedics Micropedic Therapy pillow on a hard surface?
2. Is the pressure relief on each of these surfaces sufficient enough to reduce the risk of pressure ulcers?

Hypotheses

Null: There is no significant difference between the mean seated pressure, the number of sensors activated, the variation of pressure, and the standard deviation of pressure when seated on a hard surface, a surface with a built-in cushion, and a Homedics Micropedic Therapy pillow on a hard surface.

Alternate: There is a significant difference between the mean seated pressure, the number of sensors activated, the variation of pressure, and the standard deviation of pressure when seated on a hard surface, a surface with a built-in cushion, and a Homedics Micropedic Therapy pillow on a hard surface.

CHAPTER II

LITERATURE REVIEW

The development of a pressure ulcer consists of many factors. The physiological changes of the cells and tissue, the stages of pressure ulcers, the risk factors (both intrinsic and extrinsic) associated with pressure ulcers, and the prevention and treatment options are all important components to consider when assessing a client for a proper seating surface.

The pathological progression of a pressure ulcer involves the underlying tissue structures. Pressure ulcers are more likely to occur over bony prominences where there is less tissue present. The ischial tuberosities displace the majority of weight from the upper body with pressure over this area escalating up to 300 mmHg in a sitting position.^{7,8} Between the ischial tuberosities and the seat surface, many structures are compressed including connective tissues, muscles, and the vascular and lymphatic systems.

Edema is one factor that can lead to the development of a pressure ulcer. Within the vascular system, the interstitial fluid pressure increases above the venous flow causing a decrease of fluid in the capillaries and an increase of fluid in the tissues, resulting in edema. Normal capillary pressure is approximately 32 mmHg for arteries and 12 mmHg for veins. Any pressure that exceeds normal capillary pressure puts an individual at risk for pressure ulcers.⁹ If the pressure

is not relieved within 30 minutes, tissue necrosis ensues due to a lack of tissue nutrition, increased waste products, and occlusion of the vascular and lymphatic system. Without oxygen being delivered to the cells, the tissues resort to anaerobic metabolism and a buildup of toxic byproducts occurs. This leads to tissue acidosis, increased all cell membrane permeability, edema, and cell necrosis.⁹ Additionally, capillaries begin to collapse and form thrombi leading to tissue ischemia. This breakdown in tissues results in a pressure ulcer, which can be categorized by the level of tissue destruction. Muscle tissue begins to break down if contact pressure of 60 to 70 mmHg is maintained for one to two hours. Exceeding these pressures may not lead to full thickness tissue injury; however, continued exposure to high pressure will cause skin necrosis at lower pressures.¹⁰

There are several risk factors involved in pressure ulcer development which are grouped into extrinsic and intrinsic categories. Extrinsic categories are environmental factors affecting the individual and consist of pressure, friction/shear, moisture, pressure intensity, pressure duration, and the caregiver. Intrinsic factors are internal to the individual and include impaired mobility, limitation in activity, sensory-perception alteration, older age, altered nutrition, hemodynamic alterations, emotional stress, and co-morbidity conditions.¹¹

External risk factors that can be altered are friction, shearing, pressure intensity, and duration. Friction occurs when there is movement or rubbing over a rough surface which can remove the protective outer layer of skin. Shearing causes greater damage in the deeper tissues due to the underlying tissues

moving in one direction and the more superficial tissues remaining where they are or moving more slowly than the deeper tissues. It can occur when individuals adjust their position in a chair without lifting their buttocks off the seat. These opposing actions damage subcutaneous tissue and cause tissue ischemia.⁹ As described above, elevated intensity and duration of pressure through lack of weight shifting can lead to extensive tissue damage.

Internal risk factors include existing disabilities that may impair the individual's ability to prevent and/or adhere to a treatment program for a pressure ulcer. Several medical conditions have been associated with the development of pressure ulcers. Research by Margolis, et al¹ found certain conditions involving older ambulatory patients that were associated with the risk of developing pressure ulcers. These conditions included Alzheimer's disease, congestive heart failure, chronic obstructive pulmonary disease, cerebral vascular accident, diabetes mellitus, deep venous thrombosis, hip fracture, hip surgery, limb paralysis, lower limb edema, malignancy, malnutrition, osteoporosis, Parkinson's Disease, rheumatoid arthritis, and urinary tract infections. Conditions inversely associated with pressure ulcer development were angina, hypertension, and pneumonia.¹

Another internal risk factor is decreased sensory perception which decreases the person's ability to adjust his or her position due to a lack of feeling and an inability to recognize discomfort from the increased pressure. With hypotension, or low arteriolar pressure tissue, the ability to pass fluids through the blood vessels (perfusion) may be diminished, which increases the

susceptibility of the tissue to the effects of pressure. When there is a restriction of blood flow to the area, there is a reduced ability of the arteries and capillaries to respond to pressure. On the other hand, increased blood pressure increases the risk of pressure ulcers by producing changes in the capillaries that modify the tissues susceptibility to pressure.

Decreased cognition and poor nutrition also play a role in the development of pressure ulcers since nutritional deficiencies will affect the quality and integrity of the skin.¹² Darker pigmented skin is at a higher risk for pressure ulcers because it is more difficult to detect the early signs of pressure changes relating to characteristic erythematous changes, such as redness and a reddish-blue color. Instead, the color changes in the skin of a person with darker pigment range from purple to blue.¹³

Body Mass Index, BMI, is a measurement of a person's weight scaled to the person's height. Ideal BMI for an adult is 18.5-25. A calculation below 18.5 is considered underweight and a measurement over 30 is considered obese.¹⁴ BMI has been found to have a significant correlation with average seated pressures during pressure mapping; whereas, no correlation was evident with weight or height separately.¹⁵

Decreased mobility, from age or co-morbidities, and poor hygiene, often due to incontinence, are the primary risk factors for pressure ulcers for individuals of all ages.¹⁶ With impaired mobility, the person may not have the ability to change and control his/her body position without help which increases his/her exposure to intense tissue pressure for an extended period of time. The

individual may also have difficulty with proper hygiene. Poor hygiene and incontinence can lead to increased moisture levels on the skin.¹⁶ Moisture can also develop from the temperature of the room, humidity level, and if the individual has to sit in wet clothing for a period of time. This additional moisture provides friction which further irritates the skin. It causes the skin to be easily macerated by compression due to decreased epidermal tissue tensile strength.¹⁶

Often, as people age and develop co-morbidities, their risk for pressure ulcers increases. Older age, which is an intrinsic risk factor for developing pressure ulcers, causes changes in collagen synthesis and results in tissue with lower mechanical strength and increased stiffness. Aging is also associated with decreased mobility, increased incontinence, and reduced sensory perception.¹² Overly dry skin can also become a problem by decreasing the skin's dermal pliability, leaving it more susceptible to fissure formation with pressure.^{12,16}

Once a pressure ulcer develops, there are four stages involved in categorizing the pressure ulcer. Although tissue ischemia is more often severe at deeper levels, the grading system of pressure ulcers is based on the depth of tissue necrosis that is visible. The pressure ulcer staging, from The National Pressure Ulcer Advisory Panel criteria, is recommended for health care professionals to categorize pressure ulcers.¹⁷

A Stage 1 pressure ulcer has no visible loss of tissue. The area may be painful, firm or soft, a different color, and/or a different temperature compared to the surrounding tissues. The change in color may be more difficult to observe in individuals with darker skin tones. Lack of proper intervention or a delayed

intervention at this stage will allow the pressure ulcer to cause partial thickness loss of the dermis which is classified as a Stage II pressure ulcer.¹⁷ The loss of tissue may present as either a red or pink, shallow, open ulcer with slough or a blister that is either open or closed with serum.¹⁷ The surrounding skin may be shiny with light bruising.

A Stage III pressure ulcer will have further destruction of tissue producing full thickness tissue damage which may reveal subcutaneous fat.¹⁷ At this stage, bone, tendon, or muscle tissues are not visible through the open wound but tissue damage may affect these tissues. The size of the open wound may not be the extent of the actual tissue damage as there may be undermining and tunneling.¹⁷

Once bone, tendon, or muscle tissue is exposed, the pressure ulcer is classified as Stage IV.¹⁷ This stage is the most extreme classification of a pressure ulcer. This stage also has undermining and tunneling along with slough and eschar on a portion of the wound bed.¹⁷ The extensive tissue exposure increases an individual's chance of developing osteomyelitis, which is an acute or chronic inflammatory process of the bone caused by infection.¹⁸ Osteomyelitis occurs in 38% of patients who have a Stage IV pressure ulcer.¹⁹ Eventually, sepsis can occur, causing widespread inflammation and blood clotting caused by the body's response to an infection in the ulceration.²⁰

Pressure ulcers can cause more than just physiological changes to the human body. The development of a pressure ulcer increases mortality in both acute hospitalization and long-term settings. Patients with Stage II and Stage IV

ulcers have been found to have equal mortality rates.¹⁹ Studies show that 3 to 10% of hospitalized patients are affected by pressure ulcers and 7.7 to 26.9% of patients develop a new pressure sore while in the hospital.^{4,5} These percentages are similar in the nursing home setting as well. The treatment of pressure ulcers can be a financial burden on many people as the average cost per admission of a patient to the hospital with a pressure sore can range from \$60,00 to \$78,000.^{4,5} In 2001, the cost of treating ulcers nationwide was as great as \$1.2 billion annually.^{4,5}

The cheapest and easiest way to treat pressure ulcers is prevention. Pressure mapping is an object tool to measure the interface pressures between the seated surface and the mat.²¹ Pressure mapping can assist health care professionals in deciding which interventions would be most beneficial in preventing pressure ulcers. Pressure mapping is described in greater detail in the instrumentation portion of Chapter III. In 1999, Shapcott and Levy²² produced guidelines utilizing pressure mapping to prevent pressure ulcers. If seated pressure was less than 80 mmHg at the ischial tuberosities and there were no reported problems by the patient or health care provider, no intervention was needed.²² If the readings from the pressure mapping system ranged from 80 to 120 mmHg and there was uneven pressure distribution, interventions were suggested including adjusting the cushion or trying other cushions, patient education regarding pressure relieving techniques, and adjusting wheelchair components such as the footrests, armrests, and/or seat angle.²² Pressures from 120 to 200 mmHg with uneven peaks required more detailed intervention by

health care professionals. Clinical judgment is the most valuable factor to prevent pressure ulcers especially when combined with minimizing the risk factors and providing an intervention for pressure relief.²¹

There are many ways to prevent pressure ulcers, ranging from repositioning to pressure relieving devices. Pressure relieving devices work by distributing the weight more evenly across the seated surface and decreasing moisture on the skin. The use of pressure relieving cushions was shown to be more effective than foam cushion in preventing sitting-acquired ischial pressure ulcers.²³ In a study by Yuen and Garret,²⁴ the effectiveness of the most commonly prescribed cushions were compared, consisting of the Roho, Jay, and Pindot cushions. The Roho cushion was more effective in relieving pressure at the seating surface than the Jay or Pindot cushions.²⁴ When the Jay and Roho cushions were compared to a hard sitting surface, the Roho produced more anterior shift in the center of mass than the other two surfaces and the Jay produced more lateral weight shifts.²⁵

Roho cushions have a wider variety of styles and choices when selecting a pressure relieving device. Depending on the patient's needs, a Roho cushion may cost anywhere from \$110 for a simple cushion with support only on the seated surface up to \$900 for a personal recliner cushion that gives support from the back of chair to the seated surface.²⁶ Jay cushions start at \$50 for the Jay Basic that can be used by individuals without a history of pressure ulcers and intact sensation. This cushion would primarily be used for comfort. The higher

end Jay cushion is the Jay Active, which uses Jay flow fluid instead of air and costs \$355.²⁷

There can be many different combinations used to prevent pressure ulcer formation. In addition to pressure relieving devices, different wheelchair adaptations, including tilt or recline mechanisms and passive standing, can be utilized.²² A sitting protocol, including periodic reduction of ischial pressure, will help lower the sitting load on the buttocks, especially the area close to the ischial tuberosities.²⁸ Treatment of incontinence with bowel or bladder programs or catheter placement can help decrease moisture levels which will decrease skin breakdown.

Common interventions for treating pressure ulcers include optimizing wound therapy, removal of necrotic debris, management of bacterial contamination, correction of nutritional deficits, and surgical management.¹⁹

CHAPTER III

METHODOLOGY

Subjects

This research study was performed with 35 subjects, 22 females and 13 males, between the ages of 23 and 55 years with an average age of 27.6 years. The average Body Mass Index (BMI) was 25.00 lb/in² and ranged from 18.25 lb/in² to 37.22 lb/in² (Table 1). All subjects were ambulatory, recruited from the University of North Dakota Department of Physical Therapy and included students, faculty, and staff. Posters approved by the IRB were hung in the University of North Dakota School of Medicine and Health Sciences Building (Appendix A). All participants read, signed, and gave a verbal understanding of the informed consent agreement (Appendix B). Any time a subject had a question, it was answered by the researchers to the best of their ability. All 35 subjects completed the study without any adverse effects. The study was conducted in the Department of Physical Therapy at the University of North Dakota in Grand Forks, ND. The research study was approved by the Institutional Review Board at the University of North Dakota prior to initiation of the study (Appendix C).

Table 1. Participants' Characteristics (N = 35)*

	Range	Mean \pm SD
Age (years)	23- 55	27.57 \pm 7.93
Height (inches)	60- 74.25	67.71 \pm 3.61
Weight (pounds)	119-284	164 \pm 38.18
BMI (lb/in ²)		

* Gender

Female = 22

Male = 13

Inclusion/Exclusion Criteria

Subjects were eligible for participation in the study if they met the inclusion criteria of being over the age of 18, were able to communicate discomfort, had the cognitive ability to understand directions, and did not meet any of the exclusion criteria. Exclusion criteria consisted of circulatory diseases, a history of pressure ulcers, lower extremity amputation, structural deformities that would affect sitting posture, known latex allergies, and a history of pelvic fracture. The rationale for the exclusion criteria was to maintain a standard protocol for the research procedure and to prevent any allergic reactions by exposure to latex from the seating surface.

Instrumentation

The following instrumentation was utilized during the study: consent forms, data collection sheets, a scale, a calculator, a stopwatch, an adjustable height plinth, a Homedics Micropedic Therapy pillow, a 15" x 15" x ¾" plywood

board, foot stools, a goniometer, a ruler, and the Force Sensitive Application (FSA). An instrumentation class was completed by the researchers prior to data collection for this study. Each researcher used this class to become familiar with all duties as well as her specific duty of the study to ensure reproducibility of the tasks.

A sample of the consent forms and data collection sheets are in Appendices B and D. The scale was a Detecto scale and measured the participants' weight and height, in order for the Body Mass Index (BMI) to be calculated with a calculator. The plinth used was a Motorized Hi-Lo Treatment Table purchased by the University of North Dakota Department of Physical Therapy from Tri W-G. The plinth height ranged from 18 to 37 inches. The plinth consists of 1½" firm density foam with seamless corners and had no divisions in the table surface. A ruler was used to measure the distance between the participant's popliteal fossa and edge of the pillow. A goniometer is a standard tool used to measure angles of the joints and was used to measure 90° of knee flexion. A pillow case was used as a sanitary barrier and was placed between the participant and the FSA mat with each seated surface.

The three seating surfaces were the Homedics Micropedic Therapy pillow, the plinth, and the plywood board placed on the plinth. The Homedics Micropedic Therapy pillow was purchased from the internet for \$42.94. It is filled with 100% polystyrene beads and covered with a fabric made from 85% polyester and 15% spandex (Fig. 1).

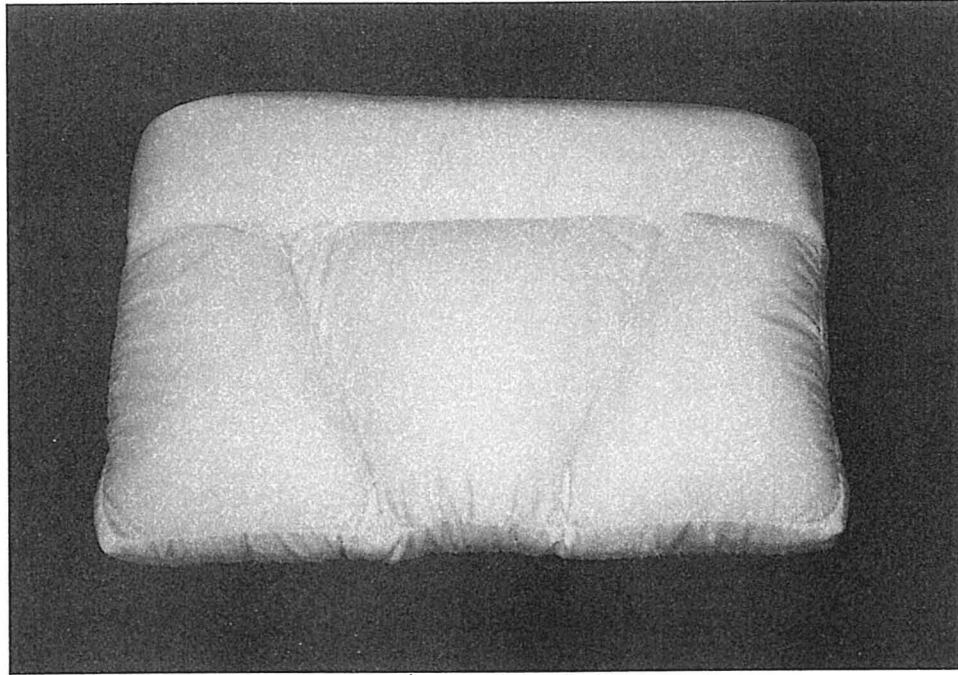


Figure 1. Homedics Micropedic Therapy Pillow

The Force Sensitive Application (FSA) pressure mapping system is a flat, thin sensor pad connected to the computer and placed under the participant on each surface (Fig. 2). It was used to map pressures in the thigh, gluteal, and sacral regions in a sitting position. The FSA is also capable of recording standing pressures occurring at the feet, although this was not included in this study. The FSA is capable of measuring pressures up to 200 mmHg. The output of the FSA includes a color-coded diagram of the pressure that occurred while the person was sitting on the sensor pad. The center of gravity is portrayed on the color-coded diagram as a black circle. Also on the output are numerical data for the sensors activated, variation coefficient, standard deviation, average pressure, maximum pressure, and center of pressure (Appendix E).



Figure 2. Force Sensitive Application Pressure Mapping System

The FSA is found to be reliable for interpreting interface pressures over a variety of surfaces.⁷ A creep effect is often demonstrated while using the FSA pressure mapping system. This causes the pressure readings to increase over time. Creep is a common occurrence with most pressure mapping systems and has been calculated as 3.3% after 2 minutes and 4.4% after 10 minutes in this system. A study shows the FSA sensor had less than 2% creep over 10 minutes at 100 mmHg, which is lower than 2 other commercially available pressure-mapping systems.²⁹ According to Stinson et al²⁰, "The FSA system has an estimated accuracy of 95% [. . .] and has been favorably described by several authors due to its easy calibration, operation, data management, and reliable measurement."

Protocol/Procedure

Each researcher performed the same task throughout the study in order to increase reliability of the measurements. Task one consisted of giving each subject the consent form, reviewing the exclusion criteria, and describing the procedure of the study. Task two consisted of asking the subjects to remove their shoes and all objects from their pockets as well as measuring and documenting the individual's height and weight in order to calculate their BMI. Task three consisted of taking all goniometric measurements at the knee to ensure 90° of knee flexion, raising and lowering the plinth, measuring the distance from the popliteal fossa to the edge of the seated surface and instructing the subject on proper sitting position. Task four consisted of running the FSA system, monitoring the sitting time on the surface, and collecting the data.

The subjects read and signed the consent form and were verbally given a description of the procedure. All subjects verbally stated they understood the procedure. They were asked if they had any of the exclusion factors mentioned previously. Information on each subject's age and sex was recorded on the data sheet along with their weight, height, and BMI (Appendix D).

The FSA sensor pad was placed on top of the Homedics Micropedic Therapy pillow and on all subsequent surfaces. The Homedics Micropedic Therapy pillow was always used as the first seating surface since there was a defined seam running the length of the pillow, allowing for standardized positioning (Figure 1). The FSA pad and Homedics Micropedic Therapy pillow

were placed on top of the plywood board and then on the plinth. The subjects were instructed to sit correctly on the first surface by placing their ischial tuberosities on the seam in the pillow. The distance from the front edge of the Homedics Micropedic Therapy pillow to the popliteal fossa was measured with a ruler and documented. This was done to standardized the popliteal angle distance from the edge of the seating surface so approximately the same amount of body surface area was in contact with the FSA sensor pad. The subject was asked to sit in an adjusted posture which consisted of sitting in a comfortable upright position with hands in the lap to eliminate distribution of weight on the arms (Figures 3A and 3B). The plinth was adjusted and goniometric measurements were taken at the subjects' knees to ensure 90° of flexion bilaterally. Feet were supported on the floor or on a stool. The height of the plinth was raised or lowered until the participant's feet were on the ground and knees were at 90° of flexion. If this position could not be met due to the short stature of the participant, a stool or stools were used to provide 90° of knee flexion and foot support. These same measurements and adjustments were repeated with the plywood board and the plinth as well.

Each subject was given 30 to 60 seconds to position him/herself in the correct posture on the chosen surface. During this time, the subject was reminded to remain still during the four minutes while the FSA was recording the data. The subject was asked to sit in the adjusted seating posture for four minutes. This amount of time was chosen as one study demonstrated that individuals who were not wheelchair bound had no significant changes in the



Figure 3A. Front view of adjusted seating posture.

output parameters on a FSA pressure mapping device after four minutes.³⁰ After recording four minutes of sitting on the pillow, the subject repeated the process on the two remaining surfaces consisting of the plywood board and the plinth. The second and third seating surfaces were randomized by printing 18 data forms with the plinth being the second surface and 18 data forms with the plywood as the second surface. These forms were numbered and shuffled numerous times. The form was then picked randomly from the stack for each subject. All intake forms were numbered to correlate with the numbering on the

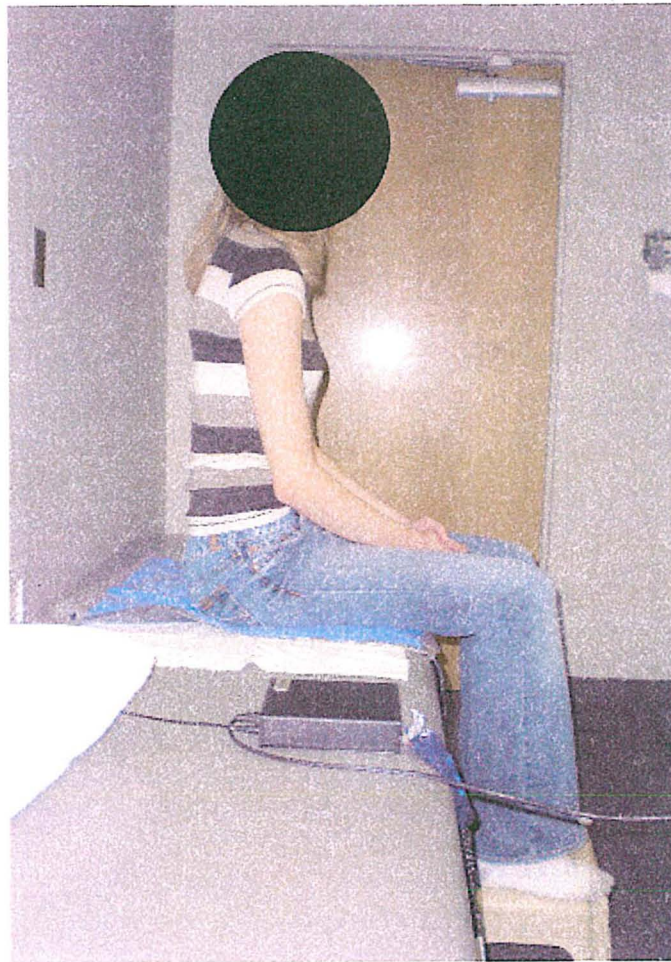


Figure 3B. Lateral view of adjusted seating posture.

computer to allow the researchers to label pressure mapping information in the FSA computer system and to correlate with data sheets consisting of the subjects' BMI, height, and weight. The data collected cannot be tied to an individual since there were no names on the intake forms and the consent forms had no numbering system.

After a review of relevant articles that compared pressure relieving cushions using the FSA pressure mapping system, the parameters taken from the FSA included the number of sensors activated, the average pressure, the

standard deviation, and the variation.^{23,24,30} The distribution of weight was determined by the number of sensors activated.³¹ The average pressure, standard deviation, and variation provides the extent to which the pressure is distributed.³² The maximum pressure was also monitored to provide information on the extent of pressure that was occurring at the ischial tuberosities. These values were recorded at the four-minute mark of each surface tested and were analyzed.

Data Analysis

Descriptive statistics were used to obtain the mean and standard deviation of age, height, weight, and BMI. A repeated measures ANOVA was used to compare the average pressure, number of sensors, variation, and standard deviation of each participant on the three different surfaces. The alpha level used throughout this research was $\alpha = .05$.

CHAPTER IV

RESULTS

After reviewing the outputs of each surface of the participants (Appendix E), data analysis was performed. Statistical analysis of the four measurements showed there was a significant difference of mean pressure ($p < .001$), number of sensors activated ($p < .001$), pressure variation ($p < .001$), and standard deviation of the pressure ($p < .001$) between the three surfaces. The means and standard deviations of the four measurements and results of the three surfaces are listed in Table 2. When comparing the Homedics Micropedic Therapy pillow and the surface with a built-in cushion to the hard surface, there was a significant decrease in the mean pressure, in pressure variation, and in standard deviation, and an increase in number of sensors activated. Statistical analysis also showed a large difference among the four measures of the three seated surfaces. The maximum pressure for all three surfaces was 200 mmHg or more providing the FSA only measures pressure up to 200 mmHg.

Bonferroni post hoc tests were performed showing a statistically significant difference among the three different surfaces for the number of sensors activated, the standard deviation of pressure, and the variation of pressure. The number of sensors activated was increased from the hard surface, the surface with a built-in cushion, and the Homedics Micropedic

Table 2. Results

	Mean	SD	F	df	Partial Eta ²	Sig.
Mean Pressure						
Pillow	48.1029	8.7631	52.746*	1,34	0.608	<.001**
Hard Surface	58.2714	13.6343				
Plinth	59.8400	10.4757				
Number of Sensors Activated						
Pillow	186.2571	17.7571	352.976	2,68	0.912	<.001**
Hard Surface	125.0857	21.9148				
Plinth	155.0571	15.2179				
SD of the Pressure						
Pillow	46.5314	6.5533	110.407	2,68	0.765	<.001**
Hard Surface	59.8686	6.7795				
Plinth	50.1943	5.9966				
Variation of the Pressure						
Pillow	97.7686	9.5566	62.809*	1,34	0.649	<.001*
Hard Surface	105.8200	15.4579				
Plinth	85.0000	9.9046				

* When sphericity was not assumed, lower bound corrections were used to obtain data.

** Sig. at $\alpha = .05$ level of significance.

Therapy pillow, respectively, implying there was the largest area of pressure distribution with the Homedics Micropedic Therapy pillow. The standard deviation and variation was decreased from the hard surface, the surface with a cushion built the Homedics Micropedic Therapy pillow, respectively, implying there was the smallest amount of standard deviation and variation in the seated pressure for the Homedics Micropedic Therapy pillow. There was a significantly lower mean pressure in the Homedics Micropedic Therapy pillow compared to the hard surface and also comparing the Homedics Micropedic Therapy pillow to the surface with a built-in cushion. These results implied that the average pressure of the whole seated surface was decreased in the Homedics Micropedic Therapy pillow. For the comparison between the hard surface and surface with a built-in cushion, there was no significant difference ($p = .418$) in mean pressure.

CHAPTER V

DISCUSSION AND CONCLUSION

When all three seating surfaces were compared, statistical significance for the mean pressure, the number of sensors activated, the variation of pressure, and the standard deviation of pressure was found. While this research suggests there was a significant difference in the pressure qualities between the three surfaces, there are still other intrinsic and extrinsic factors described in the literature review that affect the formation of pressure ulcers. These factors were not included in the study because they are individualized and standardization of the study did not include these individual changes.

The findings of this study suggest that when choosing a surface on which to sit in the everyday environment, the surface with a built-in cushion is a good alternative and has decreased pressure qualities when compared to a hard surface. This can be applied to an individual who may have decreased sensation and who may be less likely to alter his/her position while sitting.

The Homedics Micropedic Therapy pillow used as the experimental cushion for this study was effective in distributing and relieving pressure in a closed and standardized environment. According to Shapcott and Levy,²² the characteristics of a device that is sufficient at reducing the risk of pressure ulcers include good pressure distribution and no active pressure sore problems. They

also stated that the seated pressures should be less than 80 mmHg. Both the Homedics Micropedic Therapy pillow and the surface with a built-in cushion had significantly greater pressure distribution than the hard surface. Although there was a high peak pressure of 200 mmHg for all surfaces, the fact that there was good pressure distribution with the Homedics Micropedic Therapy pillow shows that it may be effective at reducing the risk of pressure ulcers. This pillow has not been tested in other environments to determine if it maintains these qualities over an extended period of time or if other factors would affect the outcome measured. Because the Homedics Micropedic Therapy pillow was designed for the head and neck for sleeping, it may limit the use of this pillow for sitting. Using the same materials, a seating pressure relieving cushion could be designed to be used specifically for sitting and would be affordable and readily available for the public.

Limitations

The study was limited by the subject selection, the accuracy of the individual research jobs, and patient movement. Subjects were selected from the University of North Dakota School of medicine and the Department of Physical Therapy. The limitation of having such a small selection sample is that the ranges of age, height, weight, and BMI were slightly skewed. These subjects were all considered “normal” subjects with no history of pressure ulcers and thus could not be compared to a subject who may have had pressure ulcers or currently had a pressure ulcer. These individuals may have an altered sitting posture due to this co-morbidity.

With this research project, each researcher had a different job that remained consistent throughout the project. Task two consisted of asking the subjects to remove all objects from their back pockets, removing their shoes, and measuring the individuals' height and weight. An error could have occurred in calculating the BMI or the subjects not removing objects from their pockets, which could have affected the results. Task three consisted of taking all goniometric measurements at the knee to ensure 90° of knee flexion, measuring the distance from the popliteal fossa to the edge of the seated surface and instructing each participant on the proper seating position. Errors could have occurred by taking inaccurate measurements or the inability to get the patient aligned identical to each seating surface.

Patient movement while the measurements were taken was difficult to avoid. Some subjects had difficulty paying attention to their body movements and they would move without conscious thought.

Suggestions for Future Research

Future research regarding pressure relieving capabilities with low cost and readily available cushions is needed. In the future, it may be helpful to assess the intrinsic and extrinsic factors that cause pressure ulcers while following the protocol of this research project with use of the Homedics Micropedic Therapy pillow. Other possibilities for research include assessing participants with a history of pressure ulcers, decreased sensation, pressure ulcers, or participants who are non-ambulatory.

Clinical Implications/Conclusion

This research project found with the use of the FSA as an objective measure that an inexpensive pressure relieving device was effective at distributing pressure when sitting. Both the Homedics Micropedic Therapy pillow and a surface with a built-in cushion were effective at relieving and distributing seated pressure, but more research is needed to determine if intrinsic and extrinsic factors will alter the results. Future research would be beneficial to determine if ambulatory individuals who are at risk for pressure ulcers should purchase a more expensive pressure relieving device or if a less expensive alternative is adequate.

APPENDIX A

Participants Needed

Study Title: Analyzing Seated Pressure On Different Surfaces Using The FSA Pressure Mapping System.

What is required of your participation?

You will be required to sit on a hard surface, a soft surface, and a pillow for 4 minutes each. Pressure readings will be taken with a mat placed on top of the seating surface.

How long will the testing take?

Only 30 minutes of your time.

When can you participate?

Contact one of the student researchers listed below to set up an appointment.

Where will the testing occur?

The study will occur in the University of North Dakota
Physical Therapy Department
Sign will be posted at the doorway.

If interested in the study please contact:

Jennifer Weber at 701-680-2713, Sara Sailer at 952-412-6008, Amber Weide at 701-471-2044, and Christine Robinson at 651-399-5731

APPENDIX B

INFORMED CONSENT

TITLE: Analyzing Seated Pressure On Different Surfaces
Using The FSA Pressure Mapping System.

PRINCIPAL INVESTIGATORS: Christine Robinson, Sara Sailer, Jennifer Weber,
Amber Weide

PROJECT DIRECTOR: Michelle LaBrecque

PHONE #: (701) 777-2831

DEPARTMENT: UND Physical Therapy Department

You are invited to be in a research study using pressure mapping to compare pressure while seated on different surfaces. The FSA pressure mapping system is a mat with pressure reading sensors. This mat is placed between your body and the surface that is being testing. It reads the amount of pressure that is exerted between the two surfaces and displays this on a computer generated image with numerical output.

The purpose of this research study is to determine if there is a significant difference between sitting pressure when seated on a hard surface, a surface with a cushion built in and a Homedics Micropedic Therapy pillow on a hard surface.

Up to 50 participants will take part in this study at the Physical Therapy Department at the University of North Dakota. Your participation in the study will last approximately 30 minutes.

Criterion for being selected for this study includes the following: 1) able to understand and follow directions, 2) able to walk without assistive devices (i.e. cane, walker, and crutches), 3) are 18 years of age or older, and 4) able to communicate discomfort.

Criterion for being excluded from the study include the following: 1) history of pressure ulcers, 2) leg amputation, 3) circulatory disease, 4) diagnosed scoliosis or other diagnosed spine abnormality, 5) latex allergies, and 6) history of pelvic fracture.

The procedure will be explained to you by the examiners. You will be asked information about your past medical history to determine if you are eligible to participate in this study. You will be asked to remove your shoes and all items from your back pockets. Your height and weight will be taken. You will be instructed to sit still in an upright position on the surface with your hands in your lap and looking forward. Measurements

University of North Dakota
Institutional Review Board

Approved on MAY 23 2007

Expires on MAY 22 2008

Subjects Initials _____
Date _____

will be taken at your knee and hip to assure proper seating position. You will be instructed to sit on each surface for 4 minutes while data is being collected.

Risks of participating in this study are minimal. An emotional risk may include your anxiety with being weighed. Another risk may be discomfort while sitting on the hard surface. In the event that this research study results in a physical injury, medical treatment will be available as it is to a member of the general public in similar circumstances. You and your third party payor must provide payment for any such treatment. The University of North Dakota, the University of North Dakota Physical Therapy department faculty or staff, and/or the researchers of this study will not be held liable for any injuries sustained during this study.

You may not benefit personally from being in this study but it is hoped that the data gathered may be used for patient education in the future. Information from this study could assist healthcare practitioners to choose the best seating surface for patients who are at a high risk for skin breakdown.

Your participation is voluntary and there will be no compensation given to you or collected from you. You may choose not to participate or you may discontinue your participation at any time during the research study without penalty. Once your data is measured and recorded, you may not withdraw your data from the study. Your decision whether or not to participate will not affect your current or future relations with the University of North Dakota. If you experience any pain, discomfort or any other symptoms detrimental to your health the experiment may be stopped.

The Physical Therapy Department at the University of North Dakota and the research team are receiving no payments from other agencies, organizations or companies to conduct this research study.

The records of this study will be kept private to the extent permitted by law. In any report about this study that might be published, you will not be identified. The records may be reviewed by Government agencies, the University of North Dakota Research Development and Compliance office and/or the University of North Dakota Institutional Review Board.

In any reports of this study, your name will not be used. Any information that is obtained in this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of a coding process. Your name will be assigned to a number and the researchers will refer to your number throughout the study. The only persons with access to the data are the researchers, statistician, and individuals who are authorized to

University of North Dakota
Institutional Review Board

Approved on MAY 23 2007

Expires on MAY 22 2008

Subjects Initials _____

Date _____

examine those procedures (Institutional Review Board auditors). The data collect and the number associated to your name will be kept in a lock cabinet for three years after which time all documents will be destroyed. If the researchers write a report or article about this study, they will describe the study results in a summarized manner so that you cannot be identified.

The researchers conducting this study are available to answer any questions or concerns you may have before, during and after this study. If you have questions, concerns, or complaints about the research after it is completed please contact Michelle LaBrecque at 701-777-2831, Christine Robinson at 651-399-5731, Sara Sailer at 952-412-6008, Jennifer Weber at 701-680-2713, or Amber Weide at 701-471-2044.

If you have questions regarding your rights as a research subject or if you have any concerns or complaints about the research, you may contact the University of North Dakota Institutional Review Board at (701) 777-4279.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you voluntarily agree to participate in this study. You will receive a copy of this form.

Subjects Name: _____

Signature of Subject

Date

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative.

Signature of Person Who Obtained Consent

Date

University of North Dakota
Institutional Review Board

Approved on MAY 23 2007

Expires on MAY 22 2008

Subjects Initials _____

Date _____

APPENDIX C

REPORT OF ACTION: EXEMPT/EXPEDITED REVIEW
University of North Dakota Institutional Review Board

Date: 5/3/2007Project Number: IRB-200705-352Principal Investigator: Robinson, Christine; Weide, Amber; Weber, Jennifer; Sailer, SaraDepartment: Physical TherapyProject Title: Analyzing Seated Pressure on Different Surfaces Using the FSA Pressure Mapping System

The above referenced project was reviewed by a designated member for the University's Institutional Review Board on May 23, 2007 and the following action was taken:

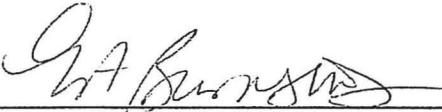
- ☒ Project approved. **Expedited Review** Category No. 4
- ☒ Next scheduled review must be before: May 22, 2008
- ☒ Copies of the attached consent form with the IRB approval stamp dated May 23, 2007 must be used in obtaining consent for this study.
- ☐ Project approved. **Exempt Review** Category No. _____
- ☐ This approval is valid until _____ as long as approved procedures are followed. No periodic review scheduled unless so stated in the Remarks Section.
- ☐ Copies of the attached consent form with the IRB approval stamp dated _____ must be used in obtaining consent for this study.
- ☐ Minor modifications required. The required corrections/additions must be submitted to RDC for review and approval. **This study may NOT be started UNTIL final IRB approval has been received.**
- ☐ Project approval deferred. **This study may not be started until final IRB approval has been received.** (See Remarks Section for further information.)
- ☐ Disapproved claim of exemption. This project requires Expedited or Full Board review. The Human Subjects Review Form must be filled out and submitted to the IRB for review.
- ☐ Proposed project is not human subject research and does not require IRB review.
- ☐ Not Research ☐ Not Human Subject

PLEASE NOTE: Requested revisions for student proposals MUST include adviser's signature. All revisions MUST be highlighted.

☒ Education Requirements Completed. (Project cannot be started until IRB education requirements are met.)

see reviewer's comments

cc: Michelle LaBrecque


 Signature of Designated IRB Member
 UND's Institutional Review Board

5/23/07
 Date

University of North Dakota Human Subjects Review Form



All research with human participants conducted by faculty, staff, and students associated with the University of North Dakota, must be reviewed and approved as prescribed by the University's policies and procedures governing the use of human subjects. It is the intent of the University of North Dakota (UND), through the Institutional Review Board (IRB) and Research Development and Compliance (RD&C), to assist investigators engaged in human subject research to conduct their research along ethical guidelines reflecting professional as well as community standards. The University has an obligation to ensure that all research involving human subjects meets regulations established by the United States Code of Federal Regulations (CFR). When completing the Human Subjects Review Form, use the "IRB Checklist" for additional guidance.

Please provide the information requested below:

Principal Investigator: Christine Robinson, Amber Weide, Jennifer Weber, Sara Sailer

Telephone: 651-399-5731
701-471-2044
701-680-2713
952-412-6008

E-mail Address: crobinson@medicine.nodak.edu,
aweide@medicine.nodak.edu,
jweber@medicine.nodak.edu,
ssailer@medicine.nodak.edu

Complete Mailing Address: 306 Tulane Ct Grand Forks, ND 58203

School/College: University of North Dakota

Department: Physical Therapy

Student Adviser (if applicable): Michelle LaBrecque, PT, DPT

Telephone: (701) 777-2831

E-mail Address: mlabrecq@medicine.nodak.edu

Address or Box #: Department of Physical Therapy, SOMHS
501 North Columbia Road Stop 9037
Grand Forks ND 58202-9037

School/College: University of North Dakota

Department: Physical Therapy

Project Title: Analyzing Seated Pressure On Different Surfaces Using The FSA Pressure Mapping System

Proposed Project Dates: Beginning Date: May 21, 2007

Completion Date: 12-20-2007

(Including data analysis)

Funding agencies supporting this research: None

Did the contract with the funding entity go through UND Grants and Contracts Administration? ☐ YES or ☒ NO
Attach a copy of the contract. Do not include the any budgetary information. The IRB will not be able to review the study without a copy of the contract with the funding agency.

Does any researcher associated with this project have an economic interest in the research, or act as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by the research? If yes, submit on a separate piece of paper an additional explanation of the financial interest. The Principal Investigator and any researcher associated with this project should have a Financial Interests Disclosure Document on file with their department.

☐ YES or ☒ NO

Will research subjects be recruited at another organization (e.g., hospitals, schools, YMCA) or will assistance with the data collection be obtained from another organization?

☐ YES or ☒ NO

If yes, list all institutions: N/A

Letters from each organization must accompany this proposal. Each letter must illustrate that the organization understands their involvement in that study, and agrees to participate in the study. Letters must include the name and title of the individual signing the letter and should be printed on letterhead.

Does any external site where the research will be conducted have its own IRB? ☐ YES ☐ NO ☒ N/A

If yes, does the external site plan to rely on UND's IRB for approval of this study? ☐ YES ☐ NO ☒ N/A
(If yes, contact the UND IRB at 701 777-4279 for additional requirements)

If your project has been or will be submitted to other IRBs, list those Boards below, along with the status of each proposal.

_____ Date submitted: _____ Status: ☐ Approved ☐ Pending
_____ Date submitted: _____ Status: ☐ Approved ☐ Pending

(include the name and address of the IRB, contact person at the IRB, and a phone number for that person)

Type of Project: Check "Yes" or "No" for each of the following.

- ☒ YES or ☐ NO New Project ☐ YES or ☒ NO Dissertation/Thesis/Independent Study
☐ YES or ☒ NO Continuation/Renewal ☒ YES or ☐ NO Student Research Project
☐ YES or ☒ NO Is this a Protocol Change for previously approved project? If yes, submit a signed copy of this form with the changes bolded or highlighted.
☐ YES or ☒ NO Does your project involve abstracting medical record information? If yes, complete the HIPAA Compliance Application and submit it with this form.
☐ YES or ☒ NO Does your project include Genetic Research?
☐ YES or ☒ NO Does your project include Internet Research?

Subject Classification: This study will involve subjects who are in the following special populations: Check all that apply.

- ☐ Children (< 18 years) ☒ UND Students
☐ Prisoners ☐ Pregnant Women/Fetuses
☐ Persons with impaired ability to understand their involvement and/or consequences of participation in this research
☐ Other _____

Please use appropriate checklist when children, prisoners, pregnant women, or people who are unable to consent will be involved in the research.

This study will involve: Check all that apply.

- ☐ Deception (Attach Waiver or Alteration of Informed Consent Requirements) ☐ Stem Cells
☐ Radiation ☐ Discarded Tissue
☐ New Drugs (IND) IND # _____ Attach Approval ☐ Fetal Tissue
☐ Investigational Device Exemption (IDE) # _____ Attach Approval ☐ Human Blood or Fluids
☐ Non-approved Use of Drug(s) ☐ Other _____
☒ None of the above will be involved in this study

I. Project Overview

Please provide a brief explanation (limit to 200 words or less) of the rationale and purpose of the study, introduction of any sponsor(s) of the study, and justification for use of human subjects and/or special populations (e.g., vulnerable populations such as children, prisoners, pregnant women/fetuses).

This research study will be using pressure mapping to compare pressure while seated on different surfaces. The FSA pressure mapping system is a mat with pressure reading sensors. This mat is placed between the subject's body and the surface being tested. It reads the amount of pressure that is exerted between the two surfaces and displays this on a computer generated image with numerical output.

The purpose of this research study is to determine if there is a significant difference between sitting pressure when seated on a hard surface, a surface with a cushion built in, and a Homedics Micropedic Therapy pillow on a hard surface.

Information from this study could assist healthcare practitioners to choose the best seating surface for patients who are at a high risk for skin breakdown. There is no known risk to human subjects in this study and the subjects represent the potential population who will benefit from the research.

II. Protocol Description

Please provide a succinct description of the procedures to be used by addressing the instructions under each of the following categories.

1. Subject Selection.

- a) Describe recruitment procedures (i.e., how subjects will be recruited, who will recruit them, where and when they will be recruited and for how long) and include copies of any advertisements, fliers, etc., that will be used to recruit subjects.
The principal investigators will recruit subjects by posting signs in the University of North Dakota Medical School during the months of May through September 2007. The subjects' participation in the study will last approximately 30 minutes each. Days will be designated June through September of 2007 as data collection dates. Each principal investigator will have her phone number posted on the recruitment signs. The participant will contact one of the principal researchers to schedule an appointment.
- b) Describe your subject selection procedures and criteria, paying special attention to the rationale for including subjects from any of the categories listed in the "Subject Classification" section above.
Subjects must be able to walk without an assistive device, be 8 years of age or older, be able to communicate discomfort, and have the cognitive ability to understand directions.
- c) Describe your exclusionary criteria and provide a rationale for excluding subject categories.
Exclusion criteria include circulatory diseases or a history of pressure ulcers, lower extremity amputation, structural deformities that would affect sitting posture, known latex allergies, and a history of pelvic fracture(s). The rationale for the exclusion criteria is to prevent an allergic reaction to the possible exposure to latex and to maintain a standard protocol for the research procedure.
- d) Describe the estimated number of subjects that will participate and the rationale for using that number of subjects.
Up to 50 subjects are expected to participate in this research study in order to increase the chances of achieving normative data so the results of the study can be compared to the general population.
- e) Specify the potential for valid results. If you have used a power analysis to determine the number of subjects, describe your method.
Valid results will be obtained by calibrating the FSA system prior to collecting data. An instrumentation class has been performed with ten subjects. This was done to familiarize the principal researchers with the equipment being utilized and the protocol..

Traditional descriptive and analytical statistics will be performed with alpha level being .05 on all tests performed.

2. Description of Methodology.

- a) Describe the procedures used to obtain informed consent.
Participants will be individually given an informed consent form on the day of testing to read and sign. Participants will then be asked to voluntarily participate in the study for approximately 30 minutes.
- b) Describe where the research will be conducted. Document the resources and facilities to be used to carry out the proposed research. Please note staffing, funding, and space available to conduct this research.
Research will be conducted at the UND Physical Therapy Department as there is adequate space to complete the testing as well as access to the pressure mapping system. All principal investigators will be involved in the data collection and research project. The student advisor will be available as needed.

- c) Indicate who will carry out the research procedures.

Each principal investigator will be responsible for certain components throughout the entire research study. One investigator will be responsible for distributing and collecting the consent form, reviewing the exclusion criteria, and describing the procedure of the study. One investigator will be responsible for removal of shoes, collecting the subjects' height and weight, and directing the subjects to the testing area. One investigator will be responsible for taking all measurements at the hip and knee to assure proper seating posture. The last investigator will be responsible for running the computer, keeping track of the time, and collecting the data. The student advisor may be present if deemed necessary.

- d) Briefly describe the procedures and techniques to be used and the amount of time that is required by the subjects to complete them.

The subject will read and sign the consent form and be able to ask any questions regarding the study. A description of the procedure will be given to each subject. The researcher will collect data on relevant past medical history on the intake form to rule out any exclusion criteria. The subject will be asked to remove all objects in his/her back pockets and shoes. The subjects' height and weight will be taken and recorded on the intake form. The time taken for the above inclusion data will take approximately five minutes. The subject will be instructed to sit on the Homedics micropedic pillow. Measurements will be taken to find the distance from the edge of the pillow's surface to the back of the knee and the knee and hip angles. These same measurements will be used on the other surfaces to standardize the area being mapped. The subject will be asked to sit in adjusted sitting posture. An adjusted sitting posture consists of altering the High/low plinth to achieve 90 ° at the knees and hips with feet on the floor. This angle at the knees and hips will be measured with a goniometer. The subject will be instructed to sit in an upright position with their hands in their lap, and looking forward. They will be asked to avoid moving or shifting during the 4 minute time period. After 4 minutes of sitting on the surface, data will be collected with the pressure mapping system. The subject will then be instructed to move to a randomly chosen seating surface of a hard board or a padded mat. The steps outlined above will be followed throughout the data collection process.

- e) Describe audio/visual procedures and proper disposal of tapes.

There will be no audio or visual procedures used during this study.

- f) Describe the qualifications of the individuals conducting all procedures used in the study.

The principal investigators are students in the doctor of Physical Therapy program at UND. All students have the appropriate background knowledge in the importance of pressure relief to prevent pressure ulcers and training in the Force Sensitive Application (FSA) pressure mapping system. An instrumentation class has been successfully completed regarding the use of the FSA pressure mapping system. The students have also received training in research methods.

- g) Describe compensation procedures (payment or class credit for the subjects, etc.).

No compensation will be given to the participants in this research study.

Attachments Necessary: Copies of all instruments (such as survey/interview questions, data collection forms completed by subjects, etc.) must be attached to this proposal.

3. Risk Identification.

- a) Clearly describe the anticipated risks to the subject/others including any physical, emotional, and financial risks that might result from this study.

The risks involved in this study are minimal. Emotional risks may include a subject's anxiety with being weighed. Another risk may be discomfort while sitting on the hard surface.

- b) Indicate whether there will be a way to link subject responses and/or data sheets to consent forms, and if so, what the justification is for having that link.
The data recorded for each subject will be confidential. Names will be number coded and will not be used in any reports of the results of this study. The only persons with access to the data are the researchers, statistician, and individuals who are authorized to examine those procedures (Institutional Review Board auditors).
- c) Provide a description of the data monitoring plan for all research that involves greater than minimal risk.
The research does not include aspects that are greater than minimal risk.
- d) If the PI will be the lead-investigator for a multi-center study, or if the PI's organization will be the lead site in a multi-center study, include information about the management of information obtained in multi-site research that might be relevant to the protection of research participants, such as unanticipated problems involving risks to participants or others, interim results, or protocol modifications.
This area is not applicable to this research study.

4. Subject Protection.

- a) Describe precautions you will take to minimize potential risks to the subjects (e.g., sterile conditions, informing subjects that some individuals may have strong emotional reactions to the procedures, debriefing, etc.).
Subjects will have the research explained to them and will be informed that participation is voluntary and may chose to quit at any time. A disposable plastic sleeve, which is designed to cover the pressure mapping pad and not interfere with the readings, will be placed over the pad to provide a protective barrier between the subject and the pad. This pad will be wiped off with a sanitary wipe after each participant completes the study testing.
- b) Describe procedures you will implement to protect confidentiality and privacy of participants (such as coding subject data, removing identifying information, reporting data in aggregate form, not violating a participants space, not intruding where one is not welcome or trusted, not observing or recording what people expect not to be public, etc.). If participants who are likely to be vulnerable to coercion and undue influence are to be included in the research, define provisions to protect the privacy and interests of these participants and additional safeguards implemented to protect the rights and welfare of these participants.
Confidentiality will be maintained by means of a coding process. The subjects' name will be assigned to a number and the researchers will refer to the number throughout the study. The only persons with access to the data are the researchers, a statistician, and individuals who are authorized to examine those procedures (Institutional Review Board auditors). The data collected and consent forms associated with the subjects will be kept in separate locked cabinets for three years after which time all documents will be destroyed. If the researchers write a report or article about this study, they will describe the study results in a summarized manner so that the subjects cannot be identified.
- c) Indicate that the subject will be provided with a copy of the consent form and how this will be done.
The subjects will have the research explained to them and will be informed that participation is voluntary and may quit at any time. Each subject will be asked to sign an informed consent form and upon agreement of the terms will be included in the study. Each subject will be given a copy of his or her consent form for future reference. The primary researchers and advisors names and telephone numbers will be given to address any questions that may arise.
- d) Describe the protocol regarding record retention. Please indicate that research data from this study and consent forms will both be retained in separate locked locations for a minimum of three years following the completion of the study.
Describe: 1) the storage location of the research data (separate from consent forms and subject personal data)
2) who will have access to the data
3) how the data will be destroyed
4) the storage location of consent forms and personal data (separate from research data)
5) how the consent forms will be destroyed

Participant records obtained from this study will be kept in a locked filing cabinet in the Physical

Therapy department at UND. The only persons with access to the data are the researchers, a statistician, and individuals who are authorized to examine those procedures (Institutional Review Board auditors). The number associated to your name will be kept in a locked cabinet for three years after which time all records will be destroyed.

- e) Describe procedures to deal with adverse reactions (referrals to helping agencies, procedures for dealing with trauma, etc.). In the event that this research study results in a physical injury, medical treatment will be available as it is to a member of the general public in similar circumstances. The subject(s) and/or their third party payor must provide payment for any such treatment. The University of North Dakota, the University of North Dakota Physical Therapy department faculty or staff, and/or the researchers of this study will not be held liable for any injuries sustained during this study.
- f) Include an explanation of medical treatment available if injury or adverse reaction occurs and responsibility for costs involved.
In the event that this research activity results in an injury, the subject(s) and/or their third party payer, if any, would provide payment for any treatment of injury. There will be no payment for participation in this study.

III. Benefits of the Study

Clearly describe the benefits to the subject and to society resulting from this study (such as learning experiences, services received, etc.). **Please note:** extra credit and/or payment are not benefits and should be listed in the Protocol Description section under Methodology.

No direct benefits to the subjects are expected. Benefits to society include suggestions or alternatives for cost effective pressure relieving products for individuals who cannot afford the traditional and often expensive products.

IV. Consent Form

A copy of the consent form must be attached to this proposal. If no consent form is to be used, document the procedures to be used to protect human subjects, and complete the Application for Waiver or Alteration of Informed Consent Requirements. Refer to form IC 701-A, Informed Consent Checklist, and make sure that all the required elements are included. **Please note:** All records attained must be retained for a period of time sufficient to meet federal, state, and local regulations; sponsor requirements; and organizational policies. The consent form must be written in language that can easily be read by the subject population and any use of jargon or technical language should be avoided. **The consent form should be written at no higher than an 8th grade reading level**, and it is recommended that it be written in the third person (please see the example on the RD&C website). A two inch by two inch blank space must be left on the bottom of each page of the consent form for the IRB approval stamp.

Necessary attachments:

- ☐ Signed Student Consent to Release of Educational Record Form (students only);
- ☐ Investigator Letter of Assurance of Compliance;
- ☐ Consent form, or Waiver or Alteration of Informed Consent Requirements (Form IC 702-B)
- ☐ Surveys, interview questions, etc. (if applicable);
- ☐ Printed web screens (if survey is over the Internet); and
- ☐ Advertisements.

By signing below, you are verifying that the information provided in the Human Subjects Review Form and attached information is accurate and that the project will be completed as indicated.

Signatures:

Jana Dailis, Jennifer Welch, Christine Robinson, Amber Deide 5-2-07
(Principal Investigator) Date:

Michelle Labrecque 5/2/07
(Student Adviser) Date:

Requirements for submitting proposals:

Additional information can be found on the IRB web site at www.und.nodak.edu/dept/orpd/regucomm/IRB/index.html.

Original Proposals and all attachments should be submitted to Research Development and Compliance, P.O. Box 7134, Grand Forks, ND 58202-7134, or brought to Room 105, Twamley Hall.

Prior to receiving IRB approval, researchers must complete the required IRB human subjects' education. Please go to <http://www.und.edu/dept/rdc/regucomm/IRB/IRBEducation.htm> for more information.

The criteria for determining what category your proposal will be reviewed under is listed on page 3 of the IRB Checklist. Your reviewer will assign a review category to your proposal. Should your protocol require full Board review, you will need to provide additional copies. Further information can be found on the RD&C website regarding required copies and IRB review categories, or you may call the RD&C office at 701 777-4279.

In cases where the proposed work is part of a proposal to a potential funding source, one copy of the completed proposal to the funding agency (agreement/contract if there is no proposal) must be attached to the completed Human Subjects Review Form if the proposal is non-clinical; 7 copies if the proposal is clinical-medical. If the proposed work is being conducted for a pharmaceutical company, 7 copies of the company's protocol must be provided.

**INVESTIGATOR LETTER OF ASSURANCE OF COMPLIANCE
WITH ALL APPLICABLE FEDERAL REGULATIONS FOR THE
PROTECTION OF THE RIGHTS OF HUMAN SUBJECTS**

Sara Sailer

I *Jennifer Weber, Christine Robinson*
(Name of Investigator)

agree that, in conducting research under the approval of the University of North Dakota Institutional Review Board, I will fully comply and assume responsibility for the enforcement of compliance with all applicable federal regulations and University policies for the protection of the rights of human subjects engaged in research. Specific regulations include the Federal Common Rule for Protection of the Rights of Human Subjects 45 CFR 46. I will also assure compliance to the ethical principles set forth in the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research document, The Belmont Report.

I understand the University's policies concerning research involving human subjects and agree to the following:

1. Should I wish to make changes in the approved protocol for this project, I will submit them for review PRIOR to initiating the changes. (A proposal may be changed without prior IRB approval where necessary to eliminate apparent immediate hazards to the subjects or others. However, the IRB must be notified in writing within 72 hours of any change, and IRB review is required at the next regularly scheduled meeting of the full IRB.)
2. If any problems involving human subjects occur, I will immediately notify the Chair of the IRB, or the IRB Coordinator.
3. I will cooperate with the UND IRB by submitting Research Project Review and Progress Reports in a timely manner.

I understand the failure to do so may result in the suspension or termination of proposed research and possible reporting to federal agencies.

Sara Sailer, Amber Weide
Jennifer Weber, Christine Robinson
Investigator Signature

5/2/07
Date

STUDENT RESEARCHERS: As of June 4, 1997 (based on the recommendation of UND Legal Counsel) the University of North Dakota IRB is unable to approve your project unless the following "Student Consent to Release of Educational Record" is signed and included with your "Human Subjects Review Form."

STUDENT CONSENT TO RELEASE OF EDUCATIONAL RECORD¹

Pursuant to the Family Educational Rights and Privacy Act of 1974, I hereby consent to the Institutional Review Board's access to those portions of my educational record which involve research that I wish to conduct under the Board's auspices. I understand that the Board may need to review my study data based on a question from a participant or under a random audit. The study to which this release pertains is Analyzing Seated Pressure on Different Surfaces Using The FSA Pressure Mapping System

I understand that such information concerning my educational record will not be released except on the condition that the Institutional Review Board will not permit any other party to have access to such information without my written consent. I also understand that this policy will be explained to those persons requesting any educational information and that this release will be kept with the study documentation.

0575471
0430854
0459079
0456830

NAID #

5-2-07

Date

Christine Robinson
Amber Weide
Jennifer Weber
Sara Sailer

Printed Name

Christine Robinson
Amber Weide
Jennifer Weber
Sara Sailer

Signature of Student Researcher

¹Consent required by 20 U.S.C. 1232g.

APPENDIX D

Collection Data

Name Code: _____

Consent form signed: YES NO

Review procedural protocol and verbal understanding was given: YES NO

Exclusion factors:

History of pressure ulcers	YES	NO
Leg amputation	YES	NO
Circulatory disease	YES	NO
Diagnosed scoliosis or other diagnosed spinal abnormalities	YES	NO
Latex allergies	YES	NO
History of pelvic fracture	YES	NO

Sex: Male Female

Age: _____

Height: _____ inches

Weight: _____ lbs.

Calculated BMI: $[\text{weight}(\text{lbs})/\text{height}(\text{inches}^2)] \times 703$ _____ lbs/inches²

First surface: Homedics Micropedic pillow
Distance between popliteal angle and pillow edge _____ inches

Second Surface: Plywood

Third Surface: Plinth

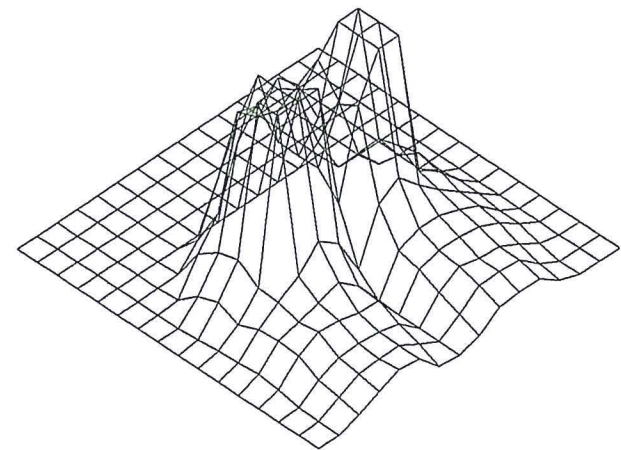
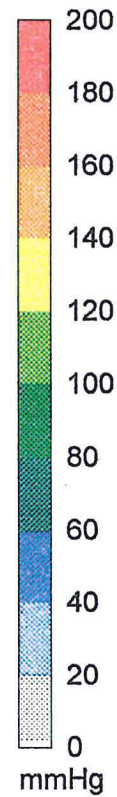
Complications during procedure: YES NO

If yes, please explain:

APPENDIX E

50

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0.8	22	71	123	105	98	97	39	0.8	0	0	0	0
7	0	0	2.4	35	62	142	143	157	136	149	94	28	3.9	0	0	0
8	0	0	19	49	147	200	120	93	117	200	200	56	27	0	0	0
9	0	2.4	27	56	200	200	186	94	144	200	200	63	42	10	0	0
10	0	4.7	17	41	200	200	200	72	156	200	200	51	39	15	0	0
11	0	6.3	26	40	53	75	58	19	71	85	64	45	31	15	0	0
12	0	7.8	27	34	39	46	29	0	38	47	46	39	30	11	0	0
13	0	6.3	27	37	35	29	28	0	32	38	38	35	25	11	0	0
14	0	1.6	16	24	25	24	18	0	23	35	31	28	17	4.7	0	0
15	0	0.8	12	21	24	24	11	0	14	30	30	28	11	0	0	0
16	0	0	7.1	17	26	24	2.4	0	6.3	21	23	23	7.8	0	0	0

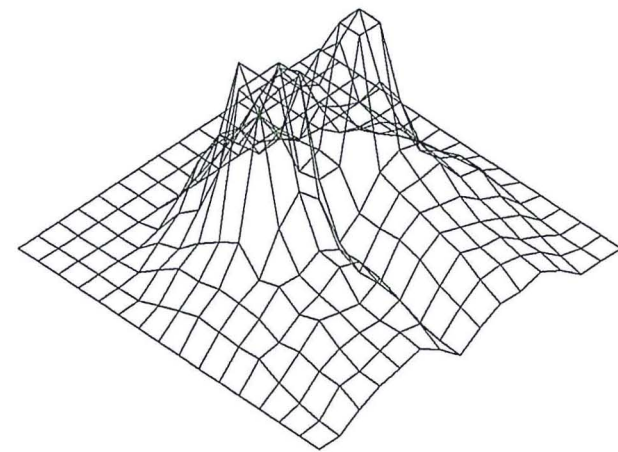
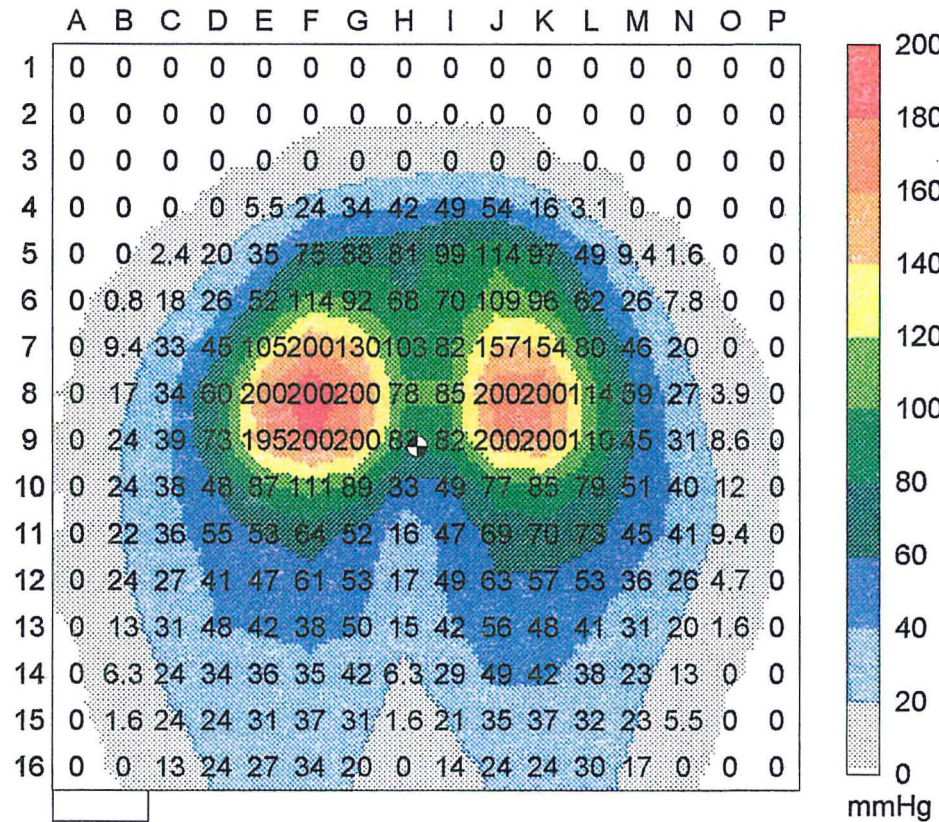


Sensors included	127
Variation coefficient	102.0%
Standard deviation	60.2
Average pressure	59
Maximum pressure	200
Center of pressure	8.1, 9.5

0005 24 May 2007 02:43:40.00PM

Example - Participant #24 - Hard Surface

51

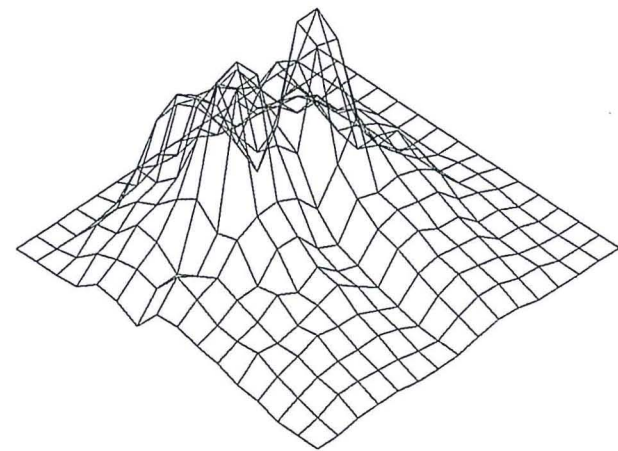
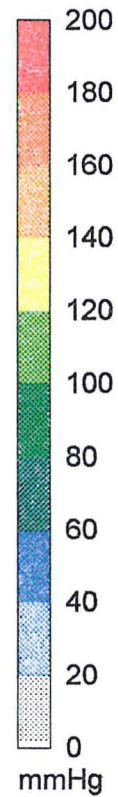


Sensors included	166
Variation coefficient	88.8%
Standard deviation	49.1
Average pressure	55.3
Maximum pressure	200
Center of pressure	8.3, 9.1

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Example - Participant #24 - Surface with Built-in Cushion

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0.8	5.5	9.4	16	13	17	6.3	0.8	0	0	0	0	0
3	0	3.9	24	27	53	88	100	85	81	65	33	21	1.6	0	0	0
4	2.4	21	29	47	53	118	109	89	112	82	53	45	32	3.9	0	0
5	17	29	51	57	71	128	99	64	100	119	83	53	27	19	0	0
6	14	33	47	76	122	166	100	50	92	134	75	37	29	17	0	0
7	3.1	27	27	89	191	200	96	109	200	200	118	32	23	1.6	0	0
8	27	52	39	69	200	200	116	95	189	183	86	59	51	9.4	0	0
9	29	42	51	75	85	87	77	53	84	119	77	58	45	9.4	5.5	0
10	24	31	42	42	66	66	41	31	63	56	59	52	38	12	7.1	0
11	20	27	34	47	36	48	31	23	46	52	47	43	23	16	5.5	0
12	11	30	26	31	37	44	28	14	39	45	34	31	13	11	0.8	0
13	7.8	20	27	34	29	27	18	8.6	28	32	29	26	9.4	7.1	0	0
14	0.8	11	19	21	20	20	13	3.1	20	27	23	17	7.1	13.1	0	0
15	0	4.7	14	14	13	10	4.7	1.6	13	19	17	10	7.8	0	0	0
16	0	0	3.9	4.7	4.7	0.8	0	0.8	5.5	9.4	7.1	1.6	0.8	0	0	0



Sensors included	200
Variation coefficient	98.6%
Standard deviation	45.1
Average pressure	45.7
Maximum pressure	200
Center of pressure	7.5, 7.6

0005 24 May 2007 02:37:55.00PM

Example - Participant #24 - Homedics Micropedic Therapy Pillow

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